

Health and Social Care Committee

Brexit: medicines, medical device and substances of human origin report

MeddiQuest Comments:

The Committee report contains scant mention of the cataclysm facing the highly innovative USD 9.5 Billion p.a. UK Medical Device Industry.

In their January "Notice to Economic Operators", the European Commission made it clear that, the approximately 25% of European Businesses, who have a UK based EU Authorised Representative or Notified Body, should be prepared to switch to an "EU-27" based provider.

Long after the publication of the EU Withdrawal Bill, there is still no hint of any mechanism by which the InVitro Diagnostic and Medical Devices Regulations can be brought into UK Law. Further, the Prime Minister's Florence Speech ruled out adopting the Implementing and Delegated Acts necessary to make such new Regulations functional, but, to us it long appeared political impossible to bring two such burdensome and disproportionate new EU Regulations into force just 8 weeks after the UK had left the EU.

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The “only game left in town” to avoid taking the UK out of a major regulatory regime, seems to be an integrated trade and regulatory deal with an increasingly protectionist U.S. Administration ... given the state of Brexit negotiations, we may have considerable concerns about our ability to conduct such a fraught negotiation.

It is a shame the Committee concentrated on the drug and biologics industry, who at least have considerable continuity of regulation assured, instead of grasping the urgent to provide the regulatory climate necessary for maintaining the UK’s position as a “centre of excellence” for medical device innovation.

Neil R Armstrong, Director and CEO

MeddiQuest

Has been based in the UK since 2001 and Peterborough since 2012 establishing itself as a leading regulatory partner for start-up, high-tech device-based healthcare companies. Since the EU Membership Referendum result, a new company has been started in Ireland which will take over the majority of the business as and when it becomes impossible to continue in the UK.

Neil Armstrong

Has over 30 years’ experience in the healthcare industries having worked on five continents. He presented on the effect of Brexit on the Medical Device Industry at the 2017 TOPRA (The Organization for Professionals in Regulatory Affairs) Symposium.

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